DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
Telephone: 781.596.7700
Facsimile: 781.596.7899

# WARNING LETTER

## NWE-12-02W

January 14, 2002

**VIA FEDERAL EXPRESS**

Reginald J. Lavoie
Administrator
Cottage Hospital
Swiftwater Road
Woodsville, NH 03785

Dear Mr. Lavoie:

We are writing to you because on November 28, 2001 and again on December 12, 2001, your facility was inspected by a representative of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

Phantom QC records were either missing or inadequately performed[1] for at least 4 weeks for Unit 1, [redacted] in the Mammo(graphy) room;

Failure to produce documents verifying that the interpreting physician, [redacted] met the initial requirement of holding a valid state license to practice medicine.

[1] No corrective actions were taken following unacceptable phantom test results for background density on 5/24, 6/9, 6/14 and 6/21/2001.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

The facility has not specified adequate procedures to be followed for infection control or did not follow them when required;

The facility has not specified adequate written procedures for collecting and resolving consumer complaints or did not follow them when required;

There is no designated audit (reviewing) interpreting physician for Cottage Hospital;

Medical audit and outcome analysis was not performed annually at Cottage Hospital;

Medical audit and outcome analysis was not done separately for each individual at site Cottage Hospital;

Medical audit and outcome analysis was not done for the facility as a whole at Cottage Hospital;

Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 1, [redacted], in the Mammo room;

Corrective actions for processor QC failures were not documented at least once for processor 1, [redacted] in the darkroom at Cottage Hospital

Documents were not produced verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (9 CEU's in 36 months);

Documents were not produced verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (3.5 CEU's in 36 months);

Documents were not produced verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (8 CEU's in 36 months);

Documents were not produced verifying that the radiologic technologist, [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months (6 CEU's in 36 months);

Documents were not produced verifying that the interpreting physician, [redacted] met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months (0 CME's in 36 months).

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** all of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

Please submit your response to: Mark Lookabaugh, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, MA 02180.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Michael Leal, MQSA Auditor at (508) 793-0422.

Sincerely yours,

Gail J. Costello
New England
District Director

cc:

[redacted]